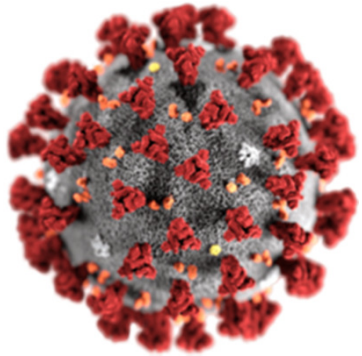
COVID-19 VACCINE
Public Health Advice

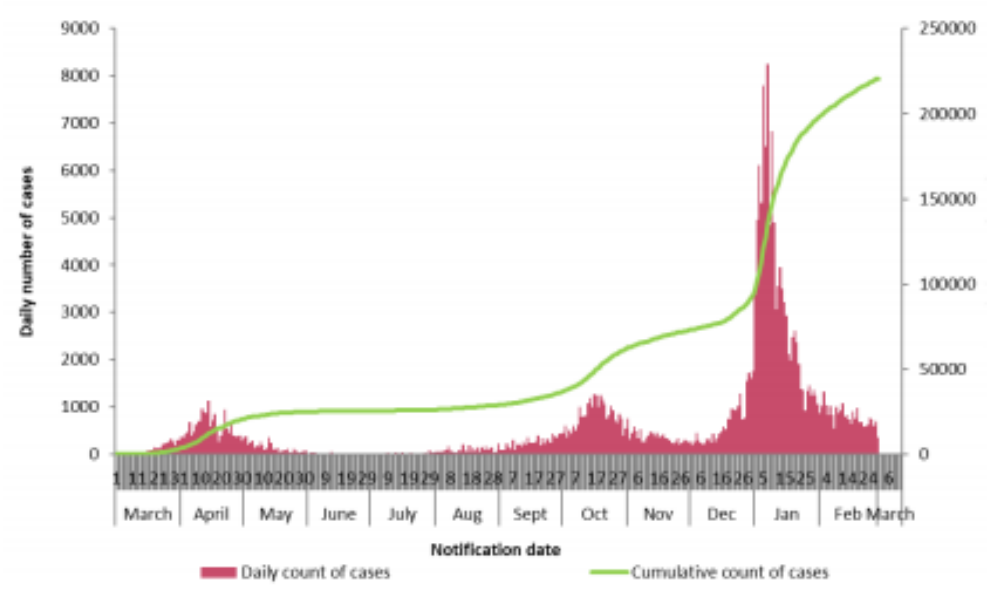
The Covid-19 Vaccination Programme

Dr Chantal Migone
Specialist in Public Health Medicine
National Immunisation Office



PROTECT PREVENT IMMUNISE

Covid-19 Epidemiology Ireland

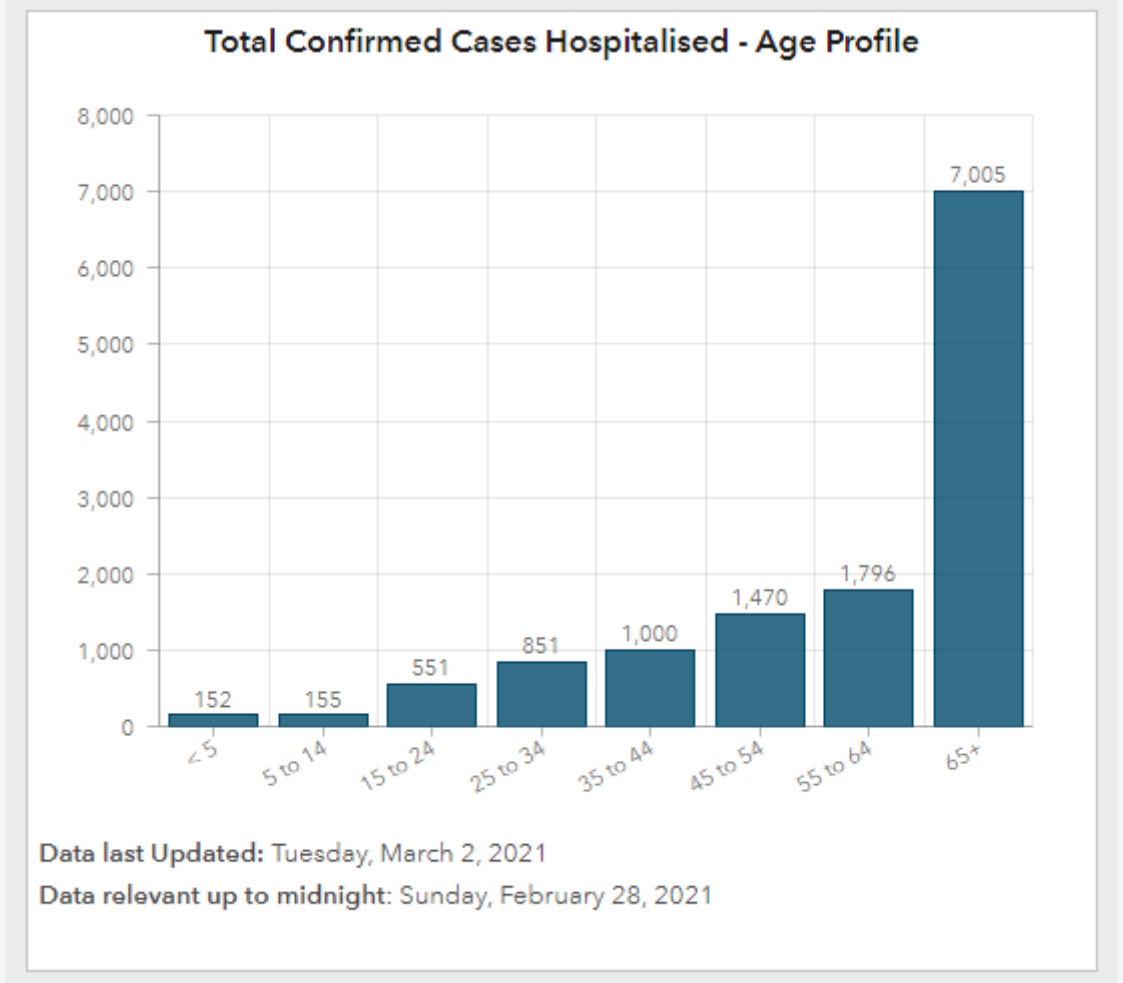


Number and cumulative number of confirmed COVID-19 cases notified in Ireland by notification date

Total Confirmed Cases
227,316
Total Deaths
4,534
(15/03/2021)

Source: Health Protection Surveillance Centre

Highest proportion of hospitalisations and deaths are in those aged 65 and older



Cases in acute hospitals:
46% had underlying medical condition

Cases in ICU:
88% had underlying medical condition

In 1st wave 56% of all deaths occurred in residents of nursing homes and long-term care facilities

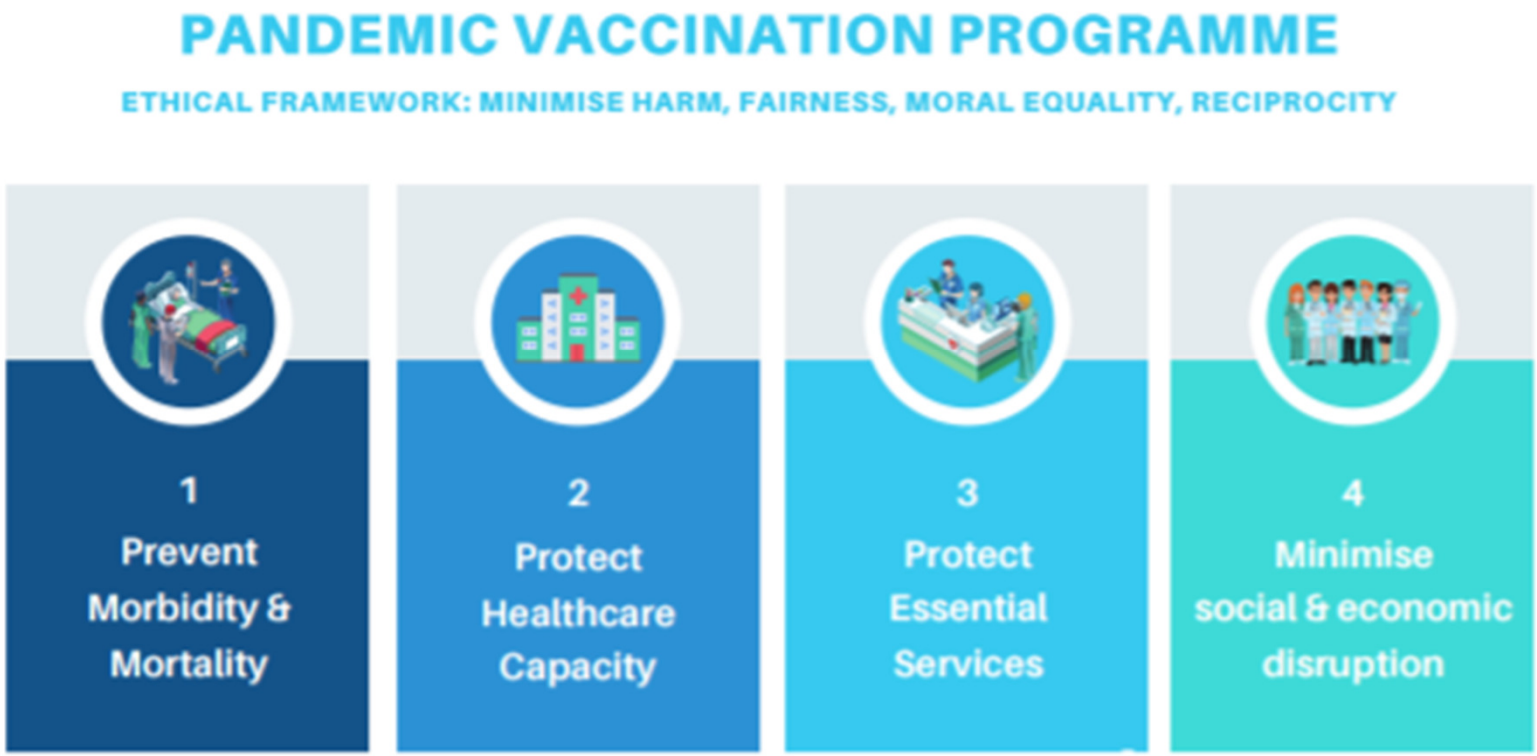
Source HPSC

https://covid19ireland-geohive.hub.arcgis.com/pages/detailed-profile-of-cases

Morbidity and mortality are higher in:

- Aged 65 years and older
- Cancer
- Chronic Heart and Vascular disease
- Chronic kidney disease
- Chronic liver disease
- Chronic neurological disease compromising clearance of respiratory secretions
- Chronic respiratory disease e.g., severe COPD, severe cystic fibrosis, severe asthma
- Diabetes
- Down syndrome
- Immuno-compromise due to disease or treatment
- Inherited metabolic diseases
- Obesity (BMI≥40)
- Intellectual Disability
- Severe mental illness

Aims of Pandemic Vaccination Programme



Priority groups

Group
Adults aged ≥65 years who are residents of long-term care facilities. Consider offering vaccination to all residents and staff on site
Frontline HCW[1] in direct patient contact roles or who risk exposure to bodily fluids or aerosols
Aged 70 and older in the following order: 85 and older 80-84 75-79 70-74
Aged 16-69 with medical conditions that put them at very high risk[2] of disease
Aged 65-69 (prioritise those with medical conditions[2] which put them at high risk of severe disease) Other HCWs not in direct patient contact Key workers

Priority groups cont.

Group
Aged 18-64 years with medical conditions[2] which put them at high risk of severe disease
Residents of long-term care facilities aged 16-64
Aged 16-64 years living or working in crowded settings where self-isolation and social distancing may be difficult to maintain
Key workers in essential jobs who cannot avoid a high risk of exposure to COVID-19. They include workers in the food supply system, public and commercial transport and other vital services
Those who are essential to education and who face disease exposure -primary and second level school staff, childcare workers, maintenance workers, school bus drivers etc.
Aged 55-64 years
Those in occupations important to the functioning of society, e.g., third level institutions, entertainment and goods-producing industries who work in settings where protective measures can be followed without much difficulty
Aged 16-54 years who did not have access to the vaccine in prior phases
Children, adolescents up to 16 years (to be refined)

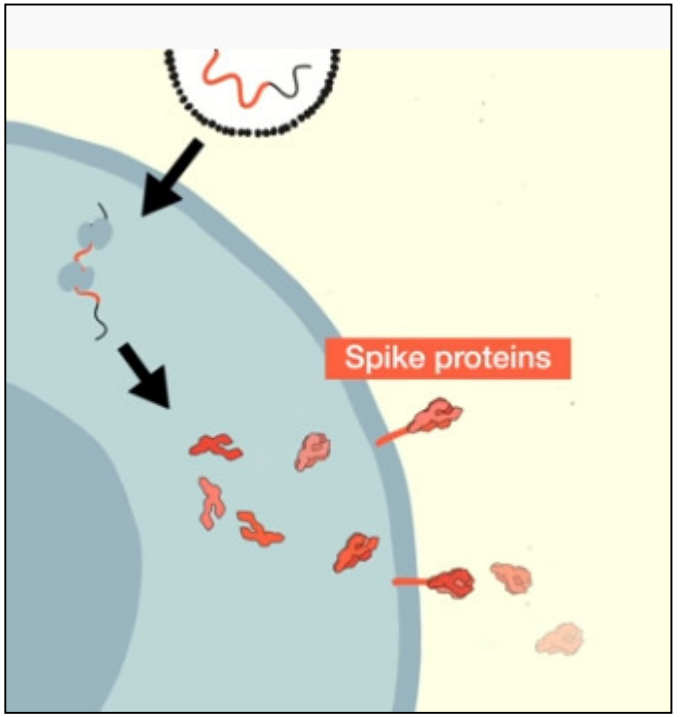
TYPES OF COVID VACCINES

Approval by EU for conditional marketing authorisation following recommendation by European Medicines Agency:

- **Comirnaty® (Pfizer/BioNTech)** 21/12/2020
- **Covid-19 Vaccine Moderna** 06/01/2021
- **Covid-19 Vaccine AstraZeneca** 29/01/2021 (paused 14/03/2021)
- **Covid-19 Vaccine Janssen** 11/03/2021 (not yet used in Ireland)

mRNA Vaccines

- The spike protein is the target antigen of the vaccines. Covid-19 vaccines stimulate the immune response against the spike protein of the virus.
- Do not contain any part of a virus. Contain mRNA, the genetic code/ blueprint to make the spike protein of the Covid -19 virus
- mRNA is coated in lipid molecules to prevent it from degrading.
- When a person is vaccinated, mRNA enters human cells and stays in the cytoplasm (it doesn't enter the nucleus). It gives instructions to the cell (ribosome) to produce the spike protein of the virus
- The spike protein is then expelled from the cell and stimulates the immune response. Antibodies are produced against the spike protein.
- mRNA is broken down a few days after the vaccine is given.
- **Not a live vaccine. Do not contain any live virus**

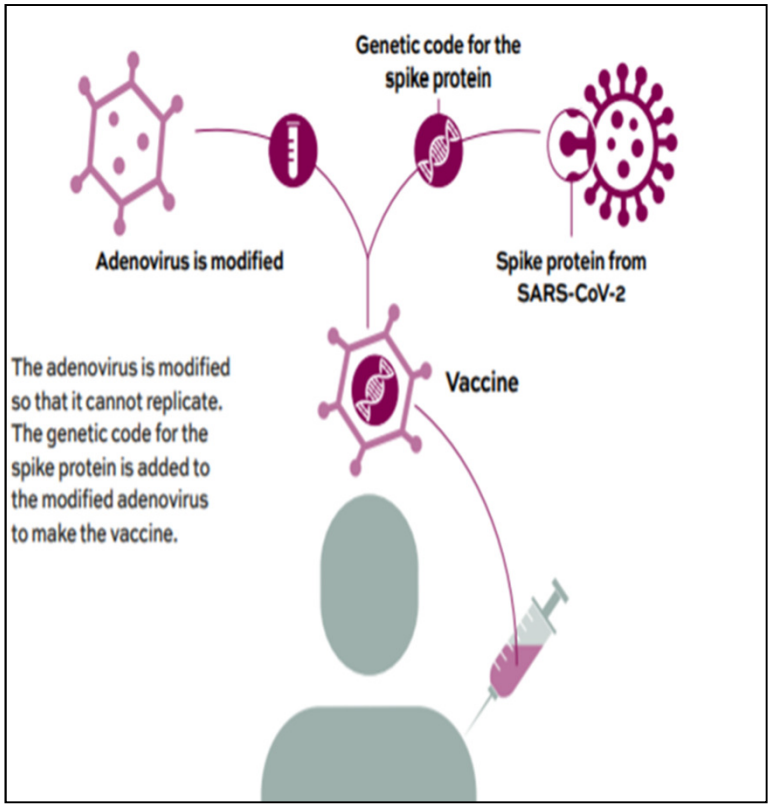


PROTECT PREVENT IMMUNISE

Viral vector vaccines

- **This vaccine is not a live vaccine and it does not contain live coronavirus.**
- Contains an adenovirus that has been modified so cannot multiply or spread throughout the body.
- The modified adenovirus (viral vector) binds to the surface of human cells and delivers the genetic code for the coronavirus spike protein, where it is processed to form the spike protein itself.
- Antibodies and immune cells (T-cells) in the circulation recognise the spike protein which stimulate the immune responses.

- The immune system subsequently forms an immune memory of the coronavirus spike protein, which facilitates quick recognition and rapid immune response in the case of future SARS-CoV-2 coronavirus exposure.



PROTECT PREVENT IMMUNISE

Vaccine efficacy mRNA Vaccines

COVID-19 VACCINE Public Health Advice

	Comirnaty	Moderna	AstraZeneca
Efficacy overall	95%	94.1%	Lancet February 2021: 82% with 12 week interval
By age **>55 & older** **≥65 to <75** **≥75**	 93.7% 92.9% 100%	 Not available 82.4% 100%	Not available
Hospitalisation or severe COVID-19 disease	1	0	100%

COVID-19 VACCINE
Public Health Advice

Adverse events

	Comirnaty® Pfizer BioNTech	COVID-19 Vaccine Moderna®	COVID-19 Vaccine AstraZeneca®
Pain at the injection site	84%	92%	54%
Fatigue	63%	70%	53%
Headache	55%	65%	53%
Myalgia and chills	38%	62%	44%, 32%
Arthralgia	24%	46%	26%
Nausea	1-10%	23%	22%
Fever	14%	16%	34% (>38°C, 8%)
Injection site redness and swelling	14%	10-15%	64%
Axillary lymphadenopathy	0.3%	>1%	
Acute peripheral facial paralysis	Rare (≥ 1/10,000 to <1/1000)		
Usually mild or moderate in intensity Resolve within a few days after vaccination	More in younger than older More after dose 2 > dose 1		More in younger than older More after dose 1>dose 2

COVID-19 VACCINE
Public Health Advice

Post vaccination observation

Anaphylaxis rate

1/100,000 Pfizer/BioNTech
1/1,000,000 Moderna

	Time of observation
Those with no history of anaphylaxis from any cause	15 minutes
Those with a history of anaphylaxis from any cause	30 minutes
Those with immediate itching, swelling or urticarial reaction at the vaccination site	30 minutes or as long as clinically indicated

COVID-19 VACCINE Public Health Advice

NIAC recommendations: Contraindications

Anaphylaxis following a previous dose of the vaccine or any of its constituents:

mRNA vaccines: including polyethylene glycol

AstraZeneca vaccine: including polysorbate 80

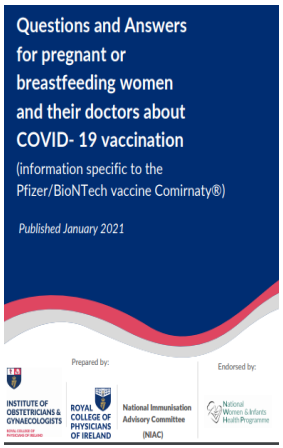
Precautions

COVID-19 VACCINE Public Health Advice

- Acute severe febrile illness
  - defer until recovery (no need to check temperature)
- Seek advice from a relevant specialist for a person with a history of an immediate systemic allergic reaction to any
  - other vaccine
  - injectable therapy
  - mRNA vaccines: polysorbate 80 (possible cross reactivity with polyethylene glycol)
- Defer until clinical recovery from COVID-19
  - at least 4 weeks after diagnosis or onset of symptoms
  - 4 weeks from first PCR positive specimen if asymptomatic
- Not contraindicated for those with persisting post COVID-19 symptoms unless recent clinical deterioration
- People who are immunosuppressed can receive COVID-19 vaccines-may not be as effective
- Patients with planned immunosuppressive therapy should ideally complete vaccination two weeks before treatment.
- No recommendation to stop any treatment prior to vaccination

Pregnancy, Breastfeeding And Fertility Treatment

- Limited experience in pregnant women. Animal studies do not indicate direct or indirect harmful effects
- NIAC recommends vaccination where it is decided that the risk/benefit is favourable. Pregnant women at high risk of severe disease and healthcare workers should discuss the risks and benefits of COVID-19 vaccine with their obstetrician or GP.
- The two dose schedule should be given between 14 and 33 weeks gestation
- COVID-19 vaccine can be given to women who are breastfeeding.
- There is no evidence the vaccine affects fertility. COVID-19 vaccines can't become part of your or your baby's DNA.
- You do not need to leave any interval after having the COVID-19 vaccine and becoming pregnant. If you become pregnant following the first dose, you should wait until 14 weeks or after to get the second dose.



COVID-19 VACCINE Public Health Advice

Adverse Events

- Over 359 million doses of COVID-19 vaccines administered globally
- 25 million UK
- 76.9 million USA
- 606,904 Ireland
- Safety profile unchanged
- Benefits outweigh the risks

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 January 2021

COVID-19 vaccine safety update

COMIRNATY
BioNTech Manufacturing GmbH

HSE

Rialtas na hÉireann
Government of Ireland

COVID-19 VACCINE
Public Health Advice

COVID-19 Vaccine AstraZeneca and thromboembolic events

- The National Immunisation Advisory Committee (NIAC) recommended pausing the administration of the COVID-19 Vaccine AstraZeneca® on 14/03/2021
- Followed a new safety alert from the Norwegian Medicines Agency
- Four new reports of serious, rare thromboembolic (clotting) events, in adults under 65 years of age
- No reports of similar events received by the HPRA to date--- 117,000 doses of COVID-19 Vaccine AstraZeneca® have been given in Ireland.
- UK MHRA 11 million doses given: continue to recommend the vaccine
- The possible relationship between these events and the COVID-19 Vaccine AstraZeneca® is uncertain and is being investigated. We do not know if the vaccine caused these events
- Clotting events are not uncommon and happen for many different reasons
- Further information is expected from the EMA in the next few days, which will include a review of the additional events.

COVID-19 VACCINE Public Health Advice

COVID-19 Vaccine AstraZeneca and thromboembolic events

- Does not affect mRNA vaccines Pfizer and Moderna
- People due to attend for AstraZeneca vaccine must not attend their appointment. Further information will be provided about second doses of AZ as soon as it is available
- People who have received the COVID-19 Vaccine AstraZeneca® and feel increasingly unwell more than three days after vaccination, and/or who notice larger or smaller blue spots in the skin (purpuric, non-blanching rash, skin haemorrhages) should consult a doctor or out-of-hours medical service. These rare events that have been reported have usually occurred within 14 days of the vaccine.
- No recommendation to take additional medication or stop current medication

COVID-19 VACCINE Public Health Advice

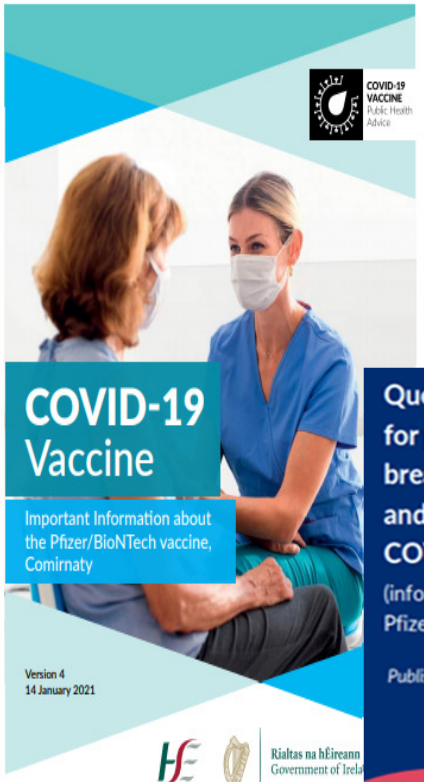
Clinical Guidance for COVID-19 Vaccination

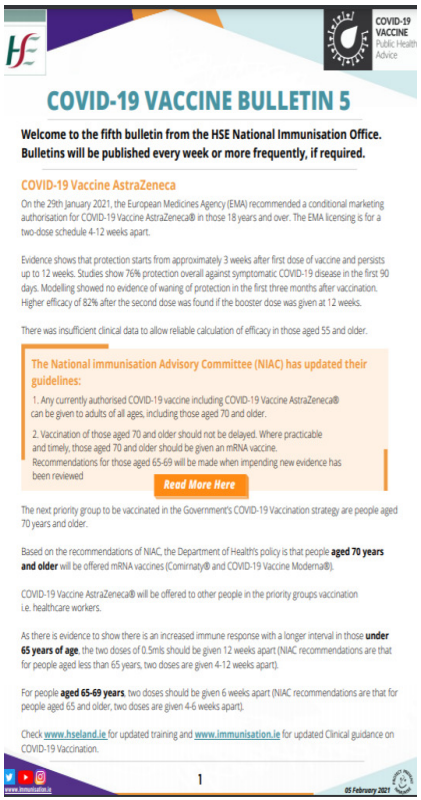
Version 5.0

5 February 2021

After your COVID-19 Vaccine Moderna

Thank you for protecting yourself and others by getting the vaccine. Now that you have had your vaccine, we ask you to read this document carefully, so you know how you can expect to feel in the next few days and where to get more information.





COVID-19 VACCINE BULLETIN 5

Welcome to the fifth bulletin from the HSE National Immunisation Office. Bulletins will be published every week or more frequently, if required.

COVID-19 Vaccine AstraZeneca

On the 29th January 2021, the European Medicines Agency (EMA) recommended a conditional marketing authorisation for COVID-19 Vaccine AstraZeneca® in those 18 years and over. The EMA licensing is for a two-dose schedule 4-12 weeks apart.

Evidence shows that protection starts from approximately 3 weeks after first dose of vaccine and persists up to 12 weeks. Studies show 76% protection overall against symptomatic COVID-19 disease in the first 90 days. Modelling showed no evidence of waning of protection in the first three months after vaccination. Higher efficacy of 82% after the second dose was found if the booster dose was given at 12 weeks.

There was insufficient clinical data to allow reliable calculation of efficacy in those aged 55 and older.

The National immunisation Advisory Committee (NIAC) has updated their guidelines:

1. Any currently authorised COVID-19 vaccine including COVID-19 Vaccine AstraZeneca® can be given to adults of all ages, including those aged 70 and older.
2. Vaccination of those aged 70 and older should not be delayed. Where practicable and timely, those aged 70 and older should be given an mRNA vaccine. Recommendations for those aged 65-69 will be made when impending new evidence has been reviewed

Read More Here

The next priority group to be vaccinated in the Government's COVID-19 Vaccination strategy are people aged 70 years and older.

Based on the recommendations of NIAC, the Department of Health's policy is that people **aged 70 years and older** will be offered mRNA vaccines (Comirnaty® and COVID-19 Vaccine Moderna®).

COVID-19 Vaccine AstraZeneca® will be offered to other people in the priority groups vaccination i.e. healthcare workers.

As there is evidence to show there is an increased immune response with a longer interval in those **under 65 years of age**, the two doses of 0.5mls should be given 12 weeks apart (NIAC recommendations are that for people aged less than 65 years, two doses are given 4-12 weeks apart).

For people **aged 65-69 years**, two doses should be given 6 weeks apart (NIAC recommendations are that for people aged 65 and older, two doses are given 4-6 weeks apart).

Check www.hseland.ie for updated training and www.immunisation.ie for updated Clinical guidance on COVID-19 Vaccination.

1

05 February 2021

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

National Immunisation Advisory Committee

Questions and Answers for pregnant or breastfeeding women and their doctors about COVID- 19 vaccination

(information specific to the Pfizer/BioNTech vaccine Comirnaty®)

Published January 2021

Prepared by: INSTITUTE OF OBSTETRICIANS & GYNAECOLOGISTS; ROYAL COLLEGE OF PHYSICIANS OF IRELAND; National Immunisation Advisory Committee (NIAC)

Endorsed by: National Women & Infants Health Programme

Rialtas na hÉireann Government of Ireland

Chapter 5a COVID-19

5a

COVID-19

SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2, SARS-COV-2

www.immunisation.ie

immunisation@hse.ie

HSE

Rialtas na hÉireann Government of Ireland